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Attorney's Docket No: 040182

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group No.: 1643

Application No.: 09/722,096

Filed: November 22, 2000

Inventor: Ernest G. Hope

ANTI-ANGIOGENIC CELLULAR  
AGENT FOR CANCER THERAPY

Examiner: Christopher H. Yaen

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT TRANSMITTAL

1. Transmitted herewith is an amendment for this application.

STATUS

2. Applicant is:

- ☒ a small entity. A statement that this filing is by a small entity is hereby asserted in accordance with the rule change effective September 8, 2000, 65 Fed. Reg. 54603.
- ☐ Other than a small entity.

## EXTENSION OF TIME

NOTE: "Extension of Time in Patent Cases (Supplement Amendments) - If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.

*If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of December 10, 1985 (1061 O.G.34-35).*

NOTE: See 37 CFR 1.645 for extensions of time in interference proceedings, and 37 CFR 1.550(c) for extensions of time in reexamination proceedings.

3. The proceedings herein are for a patent application and the provisions of 37 CFR 1.136 apply.

*(complete (a) or (b), as applicable)*

(a) ☐ Applicant petitions for an extension of time under 38 CFR 1.136  
(fees: 37 CFR 1.17(a)-(d) for the total number of months checked below:

Extension (months)	Fee for other than <u>small entity</u>	Fee for <u>small entity</u>
<input type="checkbox"/> one month	\$ 120.00	\$ 60.00
<input type="checkbox"/> two months	\$ 450.00	\$225.00
<input type="checkbox"/> three months	\$ 1,020.00	\$510.00
<input type="checkbox"/> four months	\$1,590.00	\$795.00
	<b>Fee \$</b>	<b>\$0.00</b>

If an additional extension of time is required, please consider this a petition therefor.

*(check and complete the next item, if applicable)*

☐ An extension for \_\_\_\_\_ months has already been secured and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

**OR**

(b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

### FEE FOR CLAIMS

4. The fee for claims (37 CFR 1.16(b)-(d)) has been calculated as shown below:

(Col. 1)		(Col. 2)		(Col. 3)	SMALL ENTITY		OTHER THAN A SMALL ENTITY	
CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO PREVIOUSLY PAID FOR		PRESENT EXTRA	RATE	ADDIT. FEE	OR	ADDIT. FEE
TOTAL	73*	MINUS	92**	=0	X\$25=	\$0		X\$50= \$0
INDEP.	10*	MINUS	12***	=0	X\$100=	\$0		X\$100= \$0
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+\$180=	\$0		+\$360= \$0
					TOTAL	\$0	OR	TOTAL \$0
					ADDIT. FEE			ADDIT. FEE

- \* If the entry in Col. 1 is less than entry in Col. 2, write "0" in Col. 3.  
 \*\* If the "Highest No. Previously Paid for" IN THIS SPACE is less than 20, enter "20."  
 \*\*\* If the "Highest No. Previously Paid for" IN THIS SPACE is less than 3, enter "3."  
 The "Highest No. Previously Paid for" (Total or indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

**WARNING** "After final rejection or action (§ 1.113) amendments may be made cancelling claims or complying with any requirement of form which has been made." 37 CFR § 1.116(a) (emphasis added).

*Complete (c) or (d), as applicable)*

- (c) ☒ No additional fee for claims is required.

**OR**

- (d) ☐ Total additional fee for claims required \$ 0.00

### FEE PAYMENT

5. ☐ Attached is a check in the sum of \$ 0.00.  
☐ Authorization is hereby made to charge the amount of \$ \_\_\_\_\_ to Deposit Account No. 50-3455.  
☒ Charge any additional fees required by this paper or credit any overpayment to Deposit Account No. 50-3455.

## FEE DEFICIENCY

**NOTE:** *If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).*

6. ☒ You are hereby authorized to charge Account No. 50-3455 if any additional extension fee and/or other fee is/are required under 37 C.F.R. §§ 1.16 or 1.17.

### AND/OR

- ☒ You are hereby authorized to charge Account No. 50-3455 if any additional fee for claims is required.

A duplicate of this paper is attached.

Reg. No.: 40,016

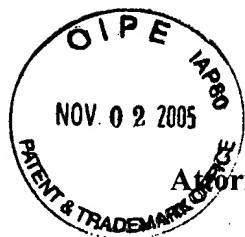
Tel. No.: (412) 421-5542

Customer No.: 52323

  
(Signature of Practitioner)

Jesse A. Hirshman  
(type or print name of attorney)

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Pittsburgh, PA 15217  
(P.O. Address)



Attorney Reference No. 040182

PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Group No.: 1643	:	
	:	
Application No.: 09/722,096	:	ANTI-ANGIOGENIC CELLULAR
	:	AGENT FOR CANCER THERAPY
	:	
Filed: November 22, 2000	:	
	:	
Inventor: Ernest G. Hope	:	Examiner: Christopher H. Yaen

**ELECTION OF SPECIES**

Pittsburgh, PA 15217  
November 2, 2005

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir,

In response to the Office Action dated October 20, 2005 (the "Action") in connection with the above-referenced Patent Application, Applicant submits the following Election of Species, with traverse.

At the outset, Applicant hereby thanks Examiner Yaen for taking the time on November 1, 2005 to discuss this requirement for election of species.

The Examiner asserts that the application contains claims directed to the following patentably distinct species of the claimed invention, wherein the cellular composition further comprises:

- a. Toxin,
- b. radioactive molecule,
- c. immune modulator,
- d. antibody, and
- e. cytokine.

In response applicant hereby elects the antibody species (d) with traverse. In the Action, the Examiner asserts that only claims 112, 113, 115, 116, 118 and 132 might read upon the elected species. Applicant respectfully requests reconsideration of this list and believes that claims 101-112, 118-154 and 158-172 read upon the elected species because they claim the cell populations of the present invention, optionally having the antibody.

As a preliminary matter, Applicant does not traverse the Examiner's election requirement on grounds that the species identified by the Examiner are not patentably distinct. No comment or admission is made herein as to the independent patentability of the listed species.

Applicant describes in the present application, and claims, for example in claim 101, and in other claims, a novel cell population and related methods. The present application provides a method of artificially manufacturing, identifying and quality assuring/quantifying EAT cells and their medicinal activity. This permits use of cell populations containing EAT-effector cells as a cellular therapy for cancer. Previously, there was no method of identifying cell populations that have the desired safety (no VLS or graft v. host disease), and effectiveness (quantifiable anti-neo-vasculature activity). Modern drugs are associated with an indication, a specific medicinal goal that the drug can achieve. In the present case, the EAT cell populations can achieve a medicinal goal only as a result of the novel discovery of their anti-neo-vasculature activity - resulting in the ability to quality-assure the desired anti-neoangiogenic activity for these artificial cell populations.

The species asserted by the Examiner are not literally species of the core invention, but embodiments of the core invention that include additional, optional, elements. The Examiner's choice of species focuses the examination on certain sub-embodiments of the invention which Applicant believes are independently patentable, but which are severely limited in scope with regard to what Applicant claims and considers the invention. The Examiner's focus on a specific embodiment, cell compositions further comprising an antibody or other agent, may lead to an examination that focuses not on the core invention, but on a specific embodiment of that core invention. Applicant believes that is improper to focus examination on the patentability of an embodiment that is not the core invention.

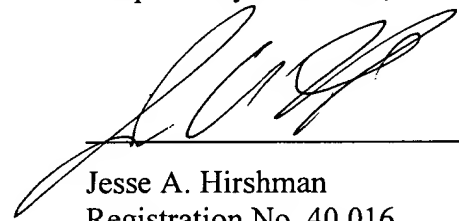
In practical terms, the Examiner's choice of species could lead to unnecessary delay and expense. If the Examiner were to allow species claim 118, would the Examiner then allow claim

101 or will we then be required to establish the independent patentability of a claim in which neither the antibody, nor any other such additional agent is necessarily present?

In reference to composition claim 101 and claims 102-141 (which depend from and add further limitation to claim 101), the present Application claims a novel cell population. Claims 111-121, upon which the Examiner focuses this Election requirement, are directed to a single sub-genus of the matter claimed in claim 101, namely cell populations further comprising an additional agent. Other than claims 111, 112 and 118, which depend directly from claim 101 and are "parent" claims to claims 113-117 and 119-121, there are thirteen other claims that depend from and further define the matter claimed in claim 101 (claims 102, 107, 109, 110, 122, 128, 131-134, 136, 137 and 140). As with claims 111-121, these thirteen other claims that depend from claim 101, and claims dependent therefrom, are directed to reasonable, non-severable sub-embodiments of the matter claimed in claim 101. As such, Applicant respectfully requests that the Examiner does not sever the embodiments presented in claims 102, 107, 109, 110, 122, 128, 131-134, 136, 137 and 140, and claims dependent therefrom, or for that matter, claim 101, from the present application by the procedural tool of an Election of Species.

Applicant traverses only to preserve the right to Petition the Director on issue(s) relating to this requirement for Election of Species and hereby expressly preserves that right. Applicant believes that claims 101-172 define over the prior art of record and are in proper form for allowance. Applicant respectfully requests allowance of claims 101-172. Applicant also requests that the Examiner call the undersigned to discuss any additional questions or concerns with respect to the above-referenced patent application.

Respectfully submitted,



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Jesse A. Hirshman  
Registration No. 40,016

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Ernest G. Hope

Application No.: 09/722,096

Filed: November 22, 2000

Group No. 1643

Examiner: Christopher H. Yaen

For: **ANTI-ANGIOGENIC CELLULAR AGENT FOR CANCER THERAPY**

**Mail Stop Amendment**

**Commissioner for Patents**

**P.O. Box 1450**

**Alexandria, VA 22313-1450**

**EXPRESS MAIL CERTIFICATE**

"Express Mail" label number: EQ002668322US

Date of Deposit: November 2, 2005

I hereby certify that the following attached paper or fee:

Amendment Transmittal (In duplicate)

Election of Species

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: **Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Jesse A. Hirshman

(typed or printed name of person mailing paper or fee)

(signature)

NOTE: Each paper must have its own certificate and the "Express Mail" label number as a part thereof or attached thereto. When, as here, the certification is presented on a separate sheet, that sheet must (1) be signed and (2) fully identify and be securely attached to the paper or fee it accompanies. Identification should include the serial number and filing date of the application as well as the type of paper being filed, e.g. complete application, specification and drawings, responses to rejection or refusal, notice of appeal, etc. If the serial number of the application is not known, the identification should include at least the name of the inventor(s) and the title of the invention.

NOTE: The label number need not be placed in each page. It should, however, be placed on the first page of each separate document, such as, a new application, amendment, assignment, and transmittal letter for a fee, along with the certificate of mailing by "Express Mail." Although the label number may be on checks, such a practice is not required. In order not to deface formal drawings it is suggested that the label number be placed on the back of each formal drawing or the drawings be accompanied by a set of informal drawings on which the label number is placed.